In the Abstract

Please substitute the following amended Abstract for the abstract as currently pending. A substitute sheet containing the amended Abstract is also provided.

Improved dip coating methods and mandrels for forming polymer leaflets and valve prostheses generally involve one or more features on the mandrel that facilitate the processing. The mandrel has a top surface and an outer surface comprising a plurality of ridges and contoured surfaces extending to the ridges. An edge on the mandrel separates the top surface and the contoured surfaces, with the mandrel edge corresponding to the free edge of the leaflet. In preferred embodiments, the edge separating the top surface from the contoured surfaces is sharp. The polymer formed on the top surface can be efficiently separated from the remaining portions of the polymer structure to form the free edges of the leaflets.

REMARKS

Claims 1-11 and 29-37 are pending. By this Amendment, claims 12-28 are canceled without prejudice in view of the restriction requirement. The title has been amended as suggested by the Examiner. Also, the abstract has been amended in view of an objection by the Examiner. New claims 30-37 are added.

New claims 30 and 31 are supported by the specification, for example, at page 28, lines 28-32. New claims 32 and 33 are supported by the specification, for example, at page 26, lines 12-20. New claims 34 and 36 are supported by the specification, for example, at page 27, lines 4-8. New claims 35 and 37 are supported by the specification, for example, at page 33, lines 1-3. No new matter is introduced by the amendments or the new claims.

All of the pending claims stand rejected. Applicants respectfully request reconsideration of the rejections based on the following comments.

Election/Restriction Requirement

The Examiner imposed a restriction under 35 U.S.C. § 121 between two claim groups. Applicants confirm without traverse their provisional telephonic election of claims 1-11

and 29. Applicants have canceled without prejudice claims 12-28 corresponding to non-elected Group II claims.

Objection To The Specification

The Examiner objected to the specification. Specifically, the Examiner objected to the abstract because legal phraseology should be avoided. While Applicants maintain that the abstract as submitted did not include legal terminology, Applicants have amended the abstract. As amended, the abstract should be clearly suitable.

Furthermore, the Examiner objected to the title as not being descriptive of the presently claimed invention. In view of the canceled claims, Applicants have adopted the Examiner's suggested title. Applicants thank the Examiner for suggesting a title.

Applicants respectfully request withdrawal of the objections to the specification.

Rejections Under 35 U.S.C. § 102(b) Over Jansen et al.

The Examiner rejected claims 1-2, 5-7 and 10 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,376,113 to Jansen et al. (the Jansen patent). Specifically, the Examiner asserted that the Jansen patent disclosed a mandrel having a plurality of ridges containing contoured surfaces therebetween for forming polymer leaflets, and further including an edge separating a top surface from the contoured surfaces, with the edge corresponding to the free edges of the heart valve. Applicants assert that the Jansen patent does not prima facie anticipate the presently claimed invention since the Jansen patent does not disclose a mandrel edge corresponding to the free edge of the leaflets. Applicants respectfully request reconsideration of the rejections based on the following comments.

Referring to Figure 1 of the Jansen patent, post (6) of Figure 1 serve as a commissure support for the attachment of the free edge of the leaflets. Consequently, the free edge of the leaflets does not extend beyond the peak of feature (6). After processing, the free edge of the Jansen heart valve will be below the mandrel edge. This is shown clearly in Figures 2 and 3 of the Jansen patent. The trimming to form the leaflets (sails in the terminology of the Jensen patent) is described, for example, at column 7, lines 19-23. Therefore, since feature (6) of the Jansen patent does not extend to the top surface (8), **the edge separating the top surface**

from the contoured surfaces does not correspond to the free edge of the leaflets. Since **the Jansen patent does not describe a mandrel edge corresponding to the free edge of the leaflets**, the Jansen patent does not render the Applicants claimed invention prima facie anticipated. Applicants respectfully request withdrawal of the rejection of claims 1-2, 5-7 and 10 under 35 U.S.C. § 102(b) as being anticipated by the Jansen patent.

Rejections Under 35 U.S.C. § 102(b) Over Pierce et al.

The Examiner rejected claims 1, 8, 11 and 29 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,364,127 to Pierce et al. (the Pierce patent). Specifically, the Examiner indicated that the Pierce patent disclosed a mandrel having a plurality of ridges extending between contoured surfaces, which form scallop regions, and a top surface formed by shims, which define an edge separating the contoured surfaces. Since the Pierce patent does not disclose a mandrel edge corresponding to a free edge of the leaflet, the Pierce patent does not prima facie anticipate the presently claimed invention. Applicants respectfully request reconsideration of the rejections based on the following comments.

The disclosure of the Pierce patent fails to teach the subject matter of claim 1 of the Applicants' invention. In particular, the disclosure of the Pierce patent does not teach a mandrel having an edge corresponding to the free edge of a leaflet. As shown clearly in Fig. 11, the free edge of the leaflet (40) is along the middle of the top of shim 35. In other words, the free edge of the leaflets is along a surface along the top of the mandrel, not along an edge. The Pierce patent also describes the cutting of adjacent leaflets to form the free edge. See, for example, column 4, lines 11-13 and corresponding Figs. 11 and 12. Since the Pierce patent does **not** disclose a mandrel with an **edge** corresponding to the free edge of the leaflet, the disclosure of the Pierce patent does not prima facie anticipate Applicants' claim 1 or any claims depending from claim 1.

With respect to claim 29 of the Applicants' invention, the disclosure of the Pierce patent fails to teach a mandrel wherein contoured surfaces corresponding to the leaflets meet contoured surfaces of adjacent leaflets at a **sharp edge**. As noted above, the Pierce patent teaches the leaflet free edges meeting along a top surface, not an edge. This is consistent with the disclosure in the Pierce patent of a subsequent processing step requiring "cutting" of the

membrane, column 4, lines 11-13. Specifically, as described in the Pierce patent, the free edges of the leaflets are located along the top of the shim not at a sharp edge, as claimed. Therefore, the disclosure of the Pierce patent does not prima facie anticipate claim 29 of the presently claimed invention.

In summary, the Pierce patent does not prima facie anticipate Applicants' claimed invention. Applicants respectfully request withdrawal of the rejection of claims 1, 8, 11 and 29 under 35 U.S.C. § 102(b) as being anticipated by the Pierce patent.

Rejections Under 35 U.S.C. § 103(a) Over Jansen et al.

The Examiner rejected claims 3-4 and 9 under 35 U.S.C. § 103(a) as being unpatentable over the Jansen patent in view of U.S. Patent 6,174,331 B1 to Moe et al. (the Moe patent). The Examiner asserted that the Jansen patent discloses the basic mandrel as claimed. The Examiner cited the Moe patent for disclosing the teaching of particular radius of curvature and an increased thickness along the edge. Applicants assert that the Moe patent does not make up for the deficiencies of the Jansen patent. Applicants respectfully request reconsideration of the rejections based on the following comments.

First, Applicants believe that there is a misunderstanding with respect to the Moe patent. The Examiner referred to "dip molding." But molding is distinct process from dip coating. Even arguendo giving a broader interpretation to molding, the term molding certainly covers much more than dip coating. The Moe patent does not teach or suggest dip coating or a mandrel. Therefore, the Moe patent clearly does not make up for the deficiencies of the Jansen patent described above with respect to Applicants' claimed invention directed to a mandrel.

Furthermore, the Examiner asserted, without support, that "it is well known that in a dip molding process a radius of curvature on the mandrel provides for improved releasability of the molded article." Applicants respectfully request support for this assertion either based on documentary evidence or an affidavit from the Examiner as required under 37 C.F.R. 1.104(d)(2). Similarly, the Examiner asserted, without support, that a dip mandrel "includes a radius of curvature in order to increase the thickness of the edge." Applicants also request documentary support for this assertion or an affidavit from the Examiner. With respect to claim 9 relating to particular features of the top surface of the mandrel, there has been a

misunderstanding with respect to the Moe patent since the Moe patent does not teach or suggest dip coating.

Since the combined teachings of the cited references do not teach or suggest a mandrel edge corresponding to the free edge of the leaflets as specified in claim 1, the cited references do not render the claims prima facie obvious. Applicants respectfully request withdrawal of the rejection of claims 3-4 and 9 under 35 U.S.C § 103 (a) as being unpatentable over the Jansen patent in view of the Moe patent.

CONCLUSION

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

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I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office, Fax No. 703-872-9310 on the date shown below thereby constituting filing of same.

Shari R. Thorndike

September 18, 2002
Date

Shari R. Thorndike

Application No. 09/724,007

ATTACHMENT

MARKED-UP AMENDMENT

In the Title

The title has been amended as follows:

MANDREL FOR DIP COATING POLYMER VALVE[S] PROSTHESES[IS] [BY DIP COATING]

In the Claims

Please cancel claims 12-28 without prejudice or disclaimer.

Please add new claims 30-37 as follows:

--30. (New) The mandrel of claim 1 wherein the top surface of the mandrel is convex.

31. (New) The mandrel of claim 1 wherein the top surface of the mandrel is concave.

32. (New) The mandrel of claim 1 comprising a groove parallel to the edge of the top surface.

33. (New) The mandrel of claim 32 wherein the groove has a depth from about 0.01 millimeter to about 1 millimeter.

34. (New) The mandrel of claim 1 wherein the mandrel edge has a radius of curvature of no more than about 0.1 millimeter.

35. (New) The mandrel of claim 1 comprising a polymer on the contoured surfaces.

36. (New) The mandrel of claim 29 wherein the sharp edge has a radius of curvature of no more than about 0.25 millimeter.

37. (New) The mandrel of claim 29 comprising a polymer on the contoured surfaces.-

In the Abstract

The Abstract has been amended as follows:

Improved dip coating methods and mandrels for forming polymer leaflets and valve prostheses [are disclosed] generally involve one or more features on the mandrel that facilitate the processing. The mandrel has a top surface and an outer surface comprising a plurality of ridges and contoured surfaces extending to the ridges. An edge on the mandrel separates the top surface and the contoured surfaces, with the mandrel edge corresponding to the free edge of the leaflet. In preferred embodiments, the edge separating the top surface from the contoured surfaces is sharp. The polymer formed on the top surface can be efficiently separated from the remaining portions of the polymer structure to form the free edges of the leaflets.